

REMARKS

Claims 1-49 are pending. Claims 1-37, 48 and 49 are rejected. Claims 38-47 are withdrawn.

Rejections under 35 U.S.C. §102

Claims 1-9, 18-22, 31, 32 and 48 are rejected as being anticipated by U.S. Patent No. 6,294,281 to Heller (“Heller”).

Claim 1 defines an electrochemical cell for use with active implantable medical devices. The electrochemical cell comprises: (a) an anode having a first immobilized enzyme deposited on a first surface of said anode, said first immobile enzyme capable of catalyzing an electrooxidation of a reducing agent; (b) a cathode having a second immobilized enzyme deposited on a second surface of said cathode, said second enzyme capable of catalyzing an electroreduction of an oxidizing agent; (c) an aqueous solution containing said reducing agent and said oxidizing agent, said solution in contact with said first immobilized enzyme and said second immobilized enzyme; and (d) a housing for providing mechanical support and electrical separation of said anode and said cathode. **The anode or cathode comprises a nanostructured material.**

Heller describes an electrochemical cell for use in an implantable device. The electrochemical cell includes an anode having an anode enzyme, a cathode having a cathode enzyme, an anode hydrogel, and a cathode hydrogel. **However, Heller does not describe an anode or cathode that comprises a nanostructured material.** Therefore, claim 1 is patentably allowable over Heller under 35 U.S.C. 102(b). Claims 2-9, 18, 19 depend from claim 1 and are patentably allowable over Heller under 35 U.S.C. §102(b) for at least the same reason.

Similar to claim 1, claims 20 and 48 both require **that the anode or cathode recited therein comprise a nanostructured material**, which Heller fails to describe or teach.

Therefore, claims 20 and 48 are patentably allowable over Heller under 35 U.S.C. 102(b).

Claims 21, 22, 31 and 32 depend from claim 20 and are patentably allowable over Heller under 35 U.S.C. §102(b) for at least the same reason.

Rejections under 35 U.S.C. §103

Claims 10-17, 23-30, 33-37, and 49 are rejected as being anticipated under 35 U.S.C. §103(a) over Heller in view of U.S. Patent No. 6,689,439 to Sobolewski ("Sobolewski"), and further in view of U.S. Patent No. 6,869,721 to Imazato ("Imazato").

Claims 10-17, 23-30, and 33-37 all define an electrochemical cell suitable for use within an implantable device. **The cell comprises an anode or cathode comprising a nanostructured material.**

Heller describes an electrochemical cell but fails to describe or teach **a cell having an anode or cathode comprising a nanostructured material.**

Sobolewski describes **a gas diffusion substrate** suitable for use within **a fuel cell**. The substrate can include **a plurality of micro-stud elements** as described therein. However, **Sobolewski does not teach an electrochemical cell.**

Imazato describes method or process for producing a gas diffusion electrode for **a oxygen/hydrogen fuel cell**. The electrode can include **a sheet-like aggregate** of carbon nanotube, which can include a catalyst layer formed thereon. The catalyst layer can include metals such as platinum, platinum alloy, palladium, magnesium, titanium, etc (cols. 3 and 4).

What leads the Examiner to combining Heller with Sobolewski and Imazato is entirely unclear to Applicants. Heller is drawn to an electrochemical cell utilizing different electrochemical potentials in different oxidation states of an electrochemical agent. In contrast, Sobolewski and Imazato are drawn to a fuel cell, utilizing the burning process of hydrogen gas in the presence of oxygen. Therefore, **the underlying mechanisms or processes for forming an electrochemical cell and a fuel cell are entirely different.** Further, in the electrochemical cell

in Heller, as well as the cell defined by claims of the instant application, enzymes are used to cause the electrochemical agent to switch between the different oxidation states. An electrochemical cell can be designed such that, upon deployment, there will be no need for additional material to generate power. **This feature is essential for use within an implantable device.** In contrast, in a fuel cell such as those described in Sobolewski or Imazato, the power source is the burning reaction of hydrogen, forming water. It is necessary to provide or replenish hydrogen gas and oxygen gas to the cell from an external gas source, e.g., a high pressure hydrogen or oxygen tank. As such, a fuel cell is **NOT SUITABLE for use within an implantable device.** Therefore, to a person of ordinary skill in the art, technical features of a fuel cell are irrelevant to an electrochemical cell as defined by Heller, which not only has a different underlying mechanism, but also has a different application or use. Heller, Sobolewski and/or Imazato and therefore not combinable.

Further, as pointed out above, a fuel cell has a different underlying process and concerns than an electrochemical cell. In addition, the electrochemical cell is suitable for use within an implantable device. Teachings of a fuel cell such as those described Sobolewski and/or Imazato may not necessarily be applicable to an electrochemical for use within an implantable device. Therefore, even if Heller, Sobolewski and/or Imazato were combinable, these references would not lead a person of ordinary skill in the art to have a reasonable expectation of success of the electrochemical cell as defined by the claims of the instant application.

In sum, claims 10-17, 23-30, and 33-37 are non-obvious over Heller in view of Sobolewski and/or Imazato under 35 U.S.C. §103(a).

Claim 49 defines a fuel cell having (a) nanostructured metal nanowires or carbon nanotube electrodes, and (b) immobilized anode and cathode enzymes deposited on the nanowires or the electrodes. **The fuel cell has a total power of about 1000 μ W to about**

10,000 μ W. Heller, Sobolewski and/or Imazato fail to provide a cell having a total power of **about 1000 μ W to about 10,000 μ W**. Therefore, claim 49 is non-obvious over Heller in view of Sobolewski and/or Imazato under 35 U.S.C. §103(a).

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.


CONCLUSION

Allowance of the claims is respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,



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